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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,704	03/09/2004	Michael Austin	S63.2-14067-US01	4218

490 7590 11/24/2008
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EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1792

MAIL DATE	DELIVERY MODE
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11/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/797,704	Applicant(s) AUSTIN ET AL.	
	Examiner Laura Edwards	Art Unit 1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 19-29 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 19-29, and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicants, via amendment to previously withdrawn claims 17 and 19-21, have effectively rejoined a withdrawn invention (a first coating system set forth in original claims 16-21) to be examined with the presently claim coating system of claim 22. Because claims 17 and 19-21 were previously withdrawn from consideration and are now rejoined with the remaining claims 22-29 and 36-38, **the restriction requirement between the two coating systems as set forth in the Office action mailed on 11/22/06 is hereby withdrawn. However, the restriction requirement between the medical device and the coating system remains.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 22, 24, 36, 37, and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Shekalim et al (US 6,971,813) for reasons set forth in the previous office action.

With respect to claims 36 and 37, Shekalim establishes the use of known coating materials including therapeutics or drugs to treat the stent in col. 2, lines 7+.

With respect to claim 38, first roller member (97) has an outer surface which is enveloped by inner cylindrical surface of holder (94).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) in view of Pacetti (US 7,175,874).

The teachings of Shekalim have been mentioned previously and while Shekalim provides for a coating system wherein coating material is separately applied and absorbed onto first roller member (97) with the first roller member then being placed adjacent second roller (92) to allow for coating material transfer to a stent, Shekalim does not teach or suggest two fluid communicating sources (i.e., two tanks or two reservoirs or main tank/sub tank) to act as a supply for coating material. However, it was known in the coating art, at the time the invention was made to provide in a stent coating material supply arrangement, the provision of separate reservoirs/tanks/sources supplied/circulated to a mixing means for subsequent application to the stent so as to allow for control in concentration of ingredients used to coat the stent as evidenced by Pacetti (col. 2, lines 47-52 and col. 3, lines 27-43). It would have been obvious to one of ordinary skill in the art to provide the stent coating material supply arrangement as taught by Pacetti in the Shekalim coating system in order to allow for control of the concentration of ingredients used to form the final composition for application to the stent.

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Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) in view of Pacetti (US 7,175,874) as applied to claim 17 above, and further in view of Layrolle et al (US 2001/0008649).

The teachings of Shekalim and Pacetti have been mentioned above but neither teach or suggest the use of one source or reservoir being a fermentor containing cells. However, it was known in the stent coating art at the time the invention was made, to provide for a source/reservoir to be in the form a fermentor system such as one used for culturing cells so as to be used to coat the stent as evidenced by Layrolle [0037]. In light of the teachings of Layrolle, one of ordinary skill in the art would readily appreciate the inclusion of at least one source having appropriate materials to effect a fermentor as one used in culturing cells to be used to apply such materials to the surface of the stent in the system as defined by the combination above as another option of therapeutic coating material for application to the stent. The inclusion of cells, as a part of a biological coating material, would be within the purview of one skilled in the art.

Claims 21, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) in view of Shibata (JP 11-111423).

With respect to claims 23, 25, and 26, these claims remain rejected for reasons set forth in the previous office action.

With respect to claim 21, Shekalim is silent concerning the use of a transfer roller arrangement wherein the surface of the second roller is grooved. However, Shibata provides a conventional coating apparatus for coating a tubular member (32) comprising a coating material source (501) containing a coating material; a first roller (201) having a surface; and a second

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roller (301) having a surface, wherein the first roller is situated relative to the coating material source so that the coating material in the coating material source can be transferred to the first roller surface; the first roller and second roller are situated relative to each other so that the first roller can transfer the coating material transferred to the first roller surface to the second roller surface, and the second roller is situated relative to the tubular member so that the second roller can transfer the coating material transferred to the second roller surface to the outer surface of the tubular member. The surface of the second roller (301) is grooved as illustrated in Fig. 4a/b relative to the smooth surface of the first roller (201). In light of the teachings of Shibata, it would have been obvious to one of ordinary skill in the art to utilize in the Shekalim coating system, a plural roller arrangement including a second grooved roller in order to control the amount of coating material applied to the stent.

Claims 27, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) in view of in view of Kirk Othmer for reasons set forth in the previous office action.

Response to Arguments

Applicant's arguments filed 8/12/08 have been fully considered but they are not persuasive.

Applicants contend that the instantly claimed invention is not anticipated by Shekalim because Shekalim does not teach the first roller situated relative to the coating material source so that coating material in the coating material source is transferred to the first roller surface.

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Shekalim merely talks about soaking sponge cartridge 97 which acts as a reservoir for the coating material to be applied to the stent.

In response to the first argument, Shekalim remains to anticipate the instantly claimed invention because the instantly claimed invention does not exclude a user from placement of the first roller in contact/communication with the coating material source. Applicants are reading the claimed invention to mean that the first roller is situated in the coating material source but Applicants have not claimed the first roller in the coating material source. Thus, the broadly written claim remains anticipated by Shekalim.

Applicants contend that Shibata fails to read on the instantly claimed invention because Shibata is non-analogous art and Shibata teaches grooves 201a in the first roller, and that conductive paste 390 oriented in the grooves 201a is transferred to the outer surface of the second roller 301. From Figure 4 of Shibata, the outer surface of the second roller appears smooth. Thus, Shibata teaches a device wherein the first roller is rougher than the second roller, and not vice versa as required by dependent claim 23.

With respect to the arguments with respect to claim 23, Shibata is analogous art as being related to a roller coating arrangement of a cylindrical member. As for the contention of the Shibata references showing a first roller rougher than the second roller, Applicants and the Examiner will agree to disagree. Shibataba establishes on the second roller (301) protrusions or projections defining grooves which would effect a second roller of a rougher surface than the first roller. Thus, Shibata remains a viable supplemental reference against claim 23.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

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November 20, 2008